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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,594	12/13/2005	Amy Newman	1173.1027P	7609
33883 7590 12/27/2007 Birch, Stewart, Kolasch & Birch, LLP 8110 Gatehouse Rd, Suite 500 East P.O. Box 747 Falls Church, VA 22040-0747				
EXAMINER JARRELL, NOBLE E				
ART UNIT		PAPER NUMBER		
1624				
MAIL DATE		DELIVERY MODE		
12/27/2007		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/527,594

**Applicant(s)**

NEWMAN ET AL.

**Examiner**

Noble Jarrell

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. Claims 1-21 are pending in the current application. This is a National Stage of PCT/US03/28895, filed 9/15/2003.

#### ***Election/Restrictions***

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, 11-13, 19-21, drawn to a method of use (treating cocaine abuse), compounds, and compositions of formula I wherein variable A is CH=CH and variable R<sub>1</sub> is phenyl.

Group II, claim(s) 1-4, 7, 11-13, 19-21, drawn to a method of use (treating cocaine abuse), compounds, and compositions of formula I wherein variable A is CH=CH and variable R<sub>1</sub> is pyridine.

Group III, claim(s) 1-4, 7, 11-13, 19-21, drawn to a method of use (treating cocaine abuse), compounds, and compositions of formula I wherein variable A is CH=CH and variable R<sub>1</sub> is quinoxaline.

Group IV, claim(s) 1-4, 7, 11-13, 19-21, drawn to a method of use (treating cocaine abuse), compounds, and compositions of formula I wherein variable A is CH=CH and variable R<sub>1</sub> is benzofuran or benzothiophene.

Group V, claim(s) 1-4, 7, 11-13, 19-21, drawn to a method of use (treating cocaine abuse), compounds, and compositions of formula I wherein variable A is CH=CH and variable R<sub>1</sub> is fluorene.

Group VI, claim(s) 1-4, 7, 11-13, 19-21, drawn to a method of use (treating cocaine abuse), compounds, and compositions of formula I not covered by groups I-V.

Group VII, claim(s) 1-6, 8, 10-12, 14, 16, 20-21, drawn to a method of use (selectively imaging dopamine D3 receptor), compounds, and compositions of formula I wherein variable A is CH=CH and variable R<sub>1</sub> is phenyl.

Group VIII, claim(s) 1-4, 8, 10-12, 14, 16, 20-21, drawn to a method of use (selectively imaging dopamine D3 receptor), compounds, and compositions of formula I wherein variable A is CH=CH and variable R<sub>1</sub> is pyridine.

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Group IX, claim(s) 1-4, 8, 10-12, 14, 16, 20-21, drawn to a method of use (selectively imaging dopamine D3 receptor), compounds, and compositions of formula I wherein variable A is CH=CH and variable R<sub>1</sub> is quinoxaline.

Group X, claim(s) 1-4, 8, 10-12, 14, 16, 20-21, drawn to a method of use (selectively imaging dopamine D3 receptor), compounds, and compositions of formula I wherein variable A is CH=CH and variable R<sub>1</sub> is benzofuran or benzothiophene.

Group XI, claim(s) 1-4, 8, 10-12, 14, 16, 20-21, drawn to a method of use (selectively imaging dopamine D3 receptor), compounds, and compositions of formula I wherein variable A is CH=CH and variable R<sub>1</sub> is fluorene.

Group XII, claim(s) 1-4, 8, 10-12, 14, 16, 20-21, drawn to a method of use (selectively imaging dopamine D3 receptor), compounds, and compositions of formula I not covered by groups VII-XI.

Group XIII, claim(s) 1-6, 9-12, 15, 17, 18, 20-21, drawn to a method of use (detecting a disease), compounds, and compositions of formula I wherein variable A is CH=CH and variable R<sub>1</sub> is phenyl.

Group XIV, claim(s) 1-4, 9-12, 15, 17, 18, 20-21, drawn to a method of use (detecting a disease), compounds, and compositions of formula I wherein variable A is CH=CH and variable R<sub>1</sub> is pyridine.

Group XV, claim(s) 1-4, 9-12, 15, 17, 18, 20-21, drawn to a method of use (detecting a disease), compounds, and compositions of formula I wherein variable A is CH=CH and variable R<sub>1</sub> is quinoxaline.

Group XVI, claim(s) 1-4, 9-12, 15, 17, 18, 20-21, drawn to a method of use (detecting a disease), compounds, and compositions of formula I wherein variable A is CH=CH and variable R<sub>1</sub> is benzofuran or benzothiophene.

Group XVII, claim(s) 1-4, 9-12, 15, 17, 18, 20-21, drawn to a method of use (detecting a disease), compounds, and compositions of formula I wherein variable A is CH=CH and variable R<sub>1</sub> is fluorene.

Group XVIII, claim(s) 1-4, 9-12, 15, 17, 18, 20-21, drawn to a method of use (detecting a disease), compounds, and compositions of formula I not covered by groups XIII-XVII.

The inventions listed as Groups I-XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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(f) "Markush practice" The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

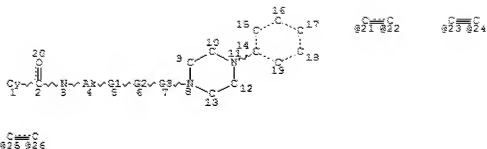
In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The different variables A, B, and R<sub>1</sub>, result in compounds that have achieved a different status in the art, and thus are drawn to an improper Markush group on the grounds of lack of a common nucleus. Thus lack of unity is apparent.

A preliminary search of a selected core gave numerous iterations, see below:

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=&gt; d que sta

L1 STR



VAP G1=21-4 22-6/23-4 24-6/CB

REF G2=(0-1) 25-6 26-7

REF G3=(0-3) C

NODE ATTRIBUTES:

DEFAULT MLEVEL IS ATOM

DEFAULT ELEVEL IS LIMITED

GRAPH ATTRIBUTES:

RING(S) ARE ISOLATED OR EMBEDDED

NUMBER OF NODES IS 26

STEREO ATTRIBUTES: NONE

L2 2 SEA FILE=REGISTRY SSS SAN L1

12.9% PROCESSED 2000 ITERATIONS

2 ANSWERS

INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)

SEARCH TIME: 00.00.01

FULL FILE PROJECTIONS: ONLINE \*\*COMPLETE\*\*

SAATCH \*\*COMPLETE\*\*

PROJECTED ITERATIONS: 803482 TO 818868

PROJECTED ANSWERS: 74 TO 846

Thus it is clear that applicant's compound core is not applicant's contribution over the prior art and the commonly shared structure does not constitute a structurally distinctive portion in view of the existing prior art. Thus there is a lack of unity.

A prior art reference anticipating the claims with respect to one group would not render obvious the same claims with respect to another group. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the

inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

3. Inventions I-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn toward different core structures due different rings for variable R<sub>1</sub> and/or different methods of use.

Claim 1 generic to the following disclosed patentably distinct species: compounds of groups I-XVIII. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected**

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**species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;



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(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so**

**may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/  
Examiner, Art Unit 1624

/James O. Wilson/  
Supervisory Patent Examiner  
Art Unit 1624